ends; a reagent pad containing all the necessary chemicals and enzymes for a specified analysis; said reagent pad being mounted to one end of said optical fiber; a detection device comprising: (a) a light emitting source; (b) a housing for engaging the other end of said fiber to said light source; (c) a photo detector to receive light reflected off the reagent pad end of said fiber; (d) a processor to convert the light signal to the analyte concentration, and (e) a display to display the test results.

16. The device of claim 15, wherein the test tip is disposable.

17. The device of claim 15, wherein the reagent pad is a membrane impregnated with dry chemicals and enzymes.

18. The device of claim 15, wherein said reagent pad is a cast polymer which contains all the required chemicals and enzymes for a specified analysis.

19. The device of claim 15, wherein the reagent pad membrane is mounted to the end of said optical fiber by an adhesive.

20. The device of claim 15, wherein said optical fiber is 0.1-2.0 mm in diameter and 5-50 mm in length, and made of glass/glass, or plastic/plastic, or glass/plastic.

21. A tubular test tip device for measuring an analyte in a sample comprising: an elongated piece of micro plastic tubing with two ends of equal size, 0.1-2.0 mm in diameter and 5-50 mm in length; a reagent pad containing all the

necessary chemicals and enzymes for a specified analysis; said reagent pad being mounted to one end of said tubing; a detection device comprising: (a) a light emitting source; (b) an elongated, non-air, fiber optic probe with two ends of equal size to transmit light, (c) a photo detector to receive light transmitted back by said fiber optic probe from reflection off the reagent pad end of said tip; (d) a processor to convert the light signal to the analyte concentration, and (e) a display to display the test results.

22. The device of claim 21, wherein the test tip is disposable.

23. The device of claim 21, wherein the reagent pad is a membrane impregnated with dry chemicals and enzymes.

24. The device of claim 21, wherein the reagent pad membrane is mounted to the end of said optical tubular tip by an adhesive.

25. The device of claim 21, wherein said reagent pad is a cast polymer which contains all the required chemicals and enzymes for a specified analysis.

26. The device of claim 21, wherein said fiber optic probe is made of glass/glass, or plastic/plastic, or glass/plastic.

Remarks

By the above amendment, Applicant has amended the title to emphasize the novelty of the invention.

Applicant has rewritten the claims to define the invention more accurately and distinctly so as to overcome the technical rejections and define the invention patentably over the prior art.

Claim Rejections – 35 USC § 102

The rejection to the claims 1-5, 8-11 and 13 under 35 U.S.C 102(b) as being anticipated by Pugh ('103)

Applicant requests reconsideration and withdrawal of this objection, as now applicable to claims 15 to 26, for the following reasons:

a) The results achieved by the present invention for minimally invasive diagnostics are new, unexpected and unsuggested by Pugh ('103).

Pugh ('103) discloses the invention to address "the risk of contamination that is posed by biological fluids and other potentially hazardous liquids" (column 2, lines 35-37). The problems present invention to address are different. The invention is to dramatically improve the current colorimetric tests used today by millions of patients, such as diabetics, for self health condition monitoring. As having been discussed in detail in the application of present invention, minimally invasive diagnostic devices greatly benefit the patients because much less an amount of biological sample is required. Minimally invasive tests are essentially painless and extremely welcome by the users. Currently, for blood glucose self monitoring, two types of blood glucose testing devices are available on the market: photometrical and electrochemical. So far, only electrochemical meters have achieved minimally invasive results. TheraSense, California, supplies an electrochemical system that requires only 0.3 μL blood for a test. For photometric method, however, there has not been a system on the market

that has achieved this result. The present invention, combining fiber optic technology and photometric chemistry, has fulfilled the niche. The devices disclosed by present invention have achieved using only 0.3 μL or less sample volume for a test as described in the patent application. These results are not mentioned or disclosed in Pugh ('103). Therefore, the present invention is considered novel and the results achieved are new, unexpected, and unsuggested by Pugh.

b) The results achieved for solving the meter contamination are superior.

Although solving the meter contamination problem is not the major goal of present invention, the result achieved on this aspect is superior to Pugh. As described at column 6, lines 29 to 43 in Pugh ('103), to solve the excess sample dripping contamination problem, either special designs as shown in Figs 12, 13, and 14, or using thick adhesives to create "gaps", have to be implemented. The present invention solved this problem without any of these because the biological sample and the non-disposable light source on the meter are distantly separated by the optical fiber and the fiber is disposed after one-time use.

c) The novelties of present invention have been recognized by Lifescan, the Assignee of Pugh ('103) patent.

Coincidently, the present invention has attracted attention of the Assignee of Pugh ('103), Lifescan, a Johnson & Johnson company. Lifescan has recognized the novelties of the invention as a possible solution to solve the invasive problem encountered in their photometric blood glucose meters. Lifescan invited the applicant to present the technologies to the company for the purpose of possible licensing or co-development of the invention. A copy of the Confidentiality Agreement signed between Applicant and Lifescan is enclosed here for reference.

d) There is a distinct difference in the design of the optical transmission system of the present invention from Pugh ('103).

The system disclosed by Pugh has two essential parts: light emitter/detector and reagent pad mounted on a disposable tip. The reflected light was transmitted to and from the reagent pad through air/space. This limits the transmission distance of the useful light signal between the light emitter/detector and reagent pad. Therefore, the distance or gap between the emitter/detector and the end of reagent pad has to be within 2-5 mm, preferably within 0.5 mm as stated in Pugh ('103) for accurate analyte measurements. The present invention has a critical component which is lacking from Pugh ('103): a solid optical fiber transmitting light between the optical sensor and the reagent pad. Since loss of light traveling through fiber optics is negligible, the disposable optical fiber tip can be made in great length and in very small diameter without losing the detection sensitivity. These two factors are critical for present invention to achieve the minimally invasive diagnostic detection results.

e) Physically, the disposable tip disclosed in Pugh ('103) must be a hollow, frustum-shaped device **with two unequal ends**. This has been emphasized by Pugh in several places in the disclosure. However, the disposable fiber optic tips disclosed in the present invention must **not** be in this shape in order for the system to function properly.

Based on these reasons, applicant submit that his invention is novel and not anticipated by Pugh ('103). Therefore, the amended claims should be allowed.

Claim Rejections – 35 USC § 103

The rejection to the claims 7 and 14 under 35 U.S.C 103(a) as being unpatentable over Pugh ('103) in view of Hauenstein et al ('727).

The disposable tip (10) in Pugh ('103) sensor system does not have an artificial light transmitting element other than natural air or space between the light source and the reagent pad. This tip (10) is merely used as a reagent pad carrier for mounting it onto the distal end (36) of the meter (30) so that cross contamination can be minimized. Adding a solid light transmitting element, such as optical fiber, between the reagent pad and the distal end (36) in Pugh's system is not necessary in solving his problem. Therefore, it would not be logical to imply or suggest the construction of optical waveguiding structures for the tip. Hauenstein et al ('727) teaches construction of a specific type of sensor for oxygen luminescent detection according to fiber optical principles. Fiber optical sensing in general has been widely known for a long time and mostly in public domain. It is only patentable if it is a new special sensor or new application. The present invention falls into this category and therefore should be patentable.

The rejection to the claims 6 and 12 under 35 U.S.C 103(a) as being unpatentable over Pugh ('103) in view of Walt et al ('490).

Claims 6 and 12 are cancelled.

Curry (4,974,929)

Curry ('929) teaches a fiber optical sensor for in vivo use. As shown in Figs. 1 and 2, the physical features are distinctly different from applicant's invention. The